UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

IN RE ZETIA (EZETIMIBE) ANTITRUST LITIGATION This document relates to: All Actions	MDL No. 2:18-md-2836

PURCHASERS' OPPOSITION TO DEFENDANTS' JOINT MOTION TO EXCLUDE PROPOSED EXPERT OPINIONS AND TESTIMONY OF PLAINTIFFS' GENERIC LAUNCH TIMING EXPERTS JON CLARK AND TODD CLARK

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The direct purchaser class plaintiffs, end-payor class plaintiffs, and retailer plaintiffs (collectively, the "purchasers") submit this joint opposition to Defendants' Joint Motion to Exclude Proposed Expert Opinions and Testimony of Plaintiffs' Generic Launch Timing Experts Jon Clark and Todd Clark (ECF No. 1040) ("Defendants' Motion") and Memorandum in Support (ECF No. 1051) ("Defs' Mem.").

I. INTRODUCTION

Based on their experience in the pharmaceutical industry, Jon Clark and Todd Clark are well qualified to render the opinions they offer in this case. Jon Clark is an FDA regulatory expert with thirty-five years of experience in the pharmaceutical industry who worked at the FDA for twenty-one years and has extensive experience working with and advising generic manufacturers seeking FDA approval. He opines on: (1) the earliest date on which Glenmark's ANDA was eligible for approval referencing Glenmark's Process I DMF; (2) the earliest date on which Glenmark's ANDA was eligible for approval referencing Glenmark's Process II DMF; (3) the earliest date on which Glenmark's ANDA was eligible for approval referencing the MSN DMF; (4) two alternative ways in which a reasonable generic manufacturer in Glenmark's position could have sought to obtain FDA approval to use MSN's API and the timing of the resulting FDA approvals; and (5) generic manufacturers' incentive to request FDA approval at the earliest opportunity.[1] Todd Clark is a pharmaceutical consultant, who has been retained by numerous

[1] PX042, Expert Report of Jon E. Clark ("J. Clark Report"), ¶¶ 3-7, 13, 104-109; PX043, Rebuttal Report of Jon E. Clark ("J. Clark Rebuttal"), at VI. Citations to PX001–PX040 herein refer to the exhibits to the August 10, 2020 Declaration of Thomas M. Sobol in Support of Purchasers' Motions for Partial Summary Judgment and to Exclude the Opinions and Testimony of Defendants' Experts (ECF Nos. 1086, 1090 & 1093); PX041-PX219 are the exhibits to the Declaration of Thomas M. Sobol in Support of Purchasers' Opposition to Merck and Glenmark Defendants' Motions for Summary Judgment, filed herewith. "MDX" numbers refer to the exhibits to the August 10, 2020 Declaration of Samuel G. Liversidge in Support of Merck's Motion for Summary Judgment (ECF Nos. 1079, 1082-1084 & 1087), and "GDX" numbers refer to the exhibits to the August 10, 2020 Declaration of Steven A. Reed in Support of the Glenmark

brand and generic drug companies, biotech firms, investment banks, and health technology services companies to offer advice on numerous issues, including regulatory compliance, drug development, and market entry. He opines on the incentives and ability of Teva Pharmaceuticals USA, Inc. and Sandoz, Inc. to introduce generic Zetia earlier absent the challenged reverse payments made by Merck to Glenmark to avoid the risk of competition and delay generic Zetia.[2]

Defendants challenge Jon Clark's opinion that a reasonable generic manufacturer in Glenmark's position, with an ANDA that is eligible for approval, would have requested final approval at its first opportunity, arguing that this opinion is unreliable because there is no basis for it and because Glenmark did not act to get approval in the way that Jon Clark opines a reasonable generic manufacturer would be expected to act. Defendants' argument is wrong both factually and legally and should be rejected by the Court. Similarly, Defendants' argument that Todd Clark's opinion should be excluded because he did not opine that Teva and Sandoz [redacted] absent Merck and Glenmark's illegal agreement is contrary to the prevailing law and also should be rejected by the Court.

II. RELEVANT REGULATORY INFORMATION

An Abbreviated New Drug Application ("ANDA") is submitted to the Food and Drug Administration ("FDA") for the review and potential approval of a generic drug product.[3] The ANDA approval process requires less time and resources than the approval process of a New Drug Application ("NDA"), largely because the ANDA applicant relies on the FDA's previous finding of safety and efficacy for the drug.[4] All drug products (whether approved via

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Defendants' Motion for Summary Judgment on All Claims (ECF Nos. 1039 & 1050).

[2] PX044, Expert Report of Todd Clark ("T. Clark Report"), ¶¶ 3-4, 15.

[3] PX042, J. Clark Report, ¶ 22.

[4] *Id.*, ¶ 26.

an NDA or an ANDA) contain one or more active pharmaceutical ingredients ("API"), which are the ingredients in the drug product that provide the pharmacological effect.[5] The API supplier and information about the quality of the API must be approved as part of the application, but is included in a separate Drug Master File ("DMF") referenced by the application.[6] DMFs are prepared and submitted to the FDA by the entity that makes the API, and generally contain all of the information required in the Chemistry, Manufacturing, and Controls (CMC) section of the ANDA with respect to the API.[7] If a company seeks to use a different API manufacturer than was previously approved by the FDA, the company must submit a supplement to its ANDA for FDA approval.[8]

An ANDA product cannot be commercially marketed until the application has received final approval from the FDA.[9] Patents and several types of exclusivities may prevent *final* approval of an ANDA.[10] Where patents or other exclusivity barriers are in place, but the FDA would otherwise approve the ANDA, the FDA grants tentative approval of the ANDA.[11] A tentative approval does not allow the applicant to market the generic drug product, and final approval will not be granted until the patent or exclusivity issues have been resolved.[12] One exclusivity that will prevent the FDA from granting a final approval of an ANDA is the 180-day marketing exclusivity of the first ANDA filer (the applicant that is first to submit a substantially

[5] *Id.*, ¶ 27.

[6] *Id.*, ¶¶ 27-28.

[7] *Id.*, ¶ 43.

[8] *Id.*, ¶ 27.

[9] *Id.*, ¶ 29.

[10] *Id.*

[11] *Id.*

[12] *Id.*

complete ANDA that contains a paragraph IV certification).[13] Subsequent ANDA filers will not be granted final approval and will not be able to market their generic drug product until expiration of the 180-day exclusivity period.[14]

III. RELEVANT FACTUAL BACKGROUND

A. Glenmark's ANDA For Generic Zetia And Its Alternate API Supplier

Glenmark filed ANDA 78560 for generic Zetia (ezetimibe) tablets, 10 mg, on October 25, 2006.[15] Glenmark's ANDA utilized API manufactured internally under DMF 19717 (the "Process I DMF").[16] Merck claimed three patents associated with Zetia, Patent Nos. 5,846,966, RE7721 and 7,030,106, and Glenmark asserted a Paragraph IV certification for all three patents.[17] Merck sued Glenmark for infringement of the RE7721 patent on March 23, 2007.[18]

On April 24, 2009, the FDA tentatively approved Glenmark's ANDA.[19] By obtaining tentative approval within 30 months of the ANDA's receipt by the FDA, Glenmark was eligible for first-to-file, 180 day exclusivity.[20] In August and September of 2011, Glenmark sought to add DMF 24825 (the "Process II DMF"), another internally manufactured API, to its ANDA.[21] Glenmark requested final approval of its ANDA on October 10, 2014, which the FDA granted on

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[13] *Id.*, ¶ 42.

[14] *Id.*

[15] PX178, Glenmark ANDA Cover Letter & 356h.

[16] PX179, Glenmark ANDA Section VIII.

[17] PX134, Patent Certification & Exclusivity Statement.

[18] PX180, Notice of Paragraph IV Certification.

[19] PX143, Glenmark Tentative Approval Letter.

[20] PX042, J. Clark Report, ¶ 71.

[21] PX165, Aug. 5, 2011 Gratuitous Preapproval Amendment; PX162, Sept. 2, 2011 Gratuitous Preapproval Amendment.

June 26, 2015.[22] In July of 2015, Glenmark filed Prior Approval Supplements seeking approval to use API manufactured by MSN Laboratories, DMF 21554 (the "MSN DMF").[23] The FDA approved Glenmark's requests to add the MSN DMF in early September of 2015.[24]

As early as 2007 and 2008, even as Glenmark sought to develop API internally, it was exploring external sources of API.[25] By 2008, Glenmark received pricing from MSN for both R&D and commercial lots of API.[26] Glenmark shared its internal API specifications with MSN in early 2010 and received and evaluated three sample lots of MSN API by July of 2010.[27] Glenmark had no issue with the quality of the MSN API at this time.[28] In June and July of 2011, Glenmark and MSN engaged in negotiations for MSN to supply ezetimibe API.[29] Between June of 2011 and November of 2011, MSN manufactured 4 batches (70.8 Kg) of ezetimibe API, which were sufficient to support the exhibit batches necessary for Glenmark to add MSN as an alternate API supplier.[30]

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[22] PX167, Glenmark Minor Amendment & Final Approval Request; PX145, Glenmark Final Approval Letter.

[23] PX154, July 7, 2015 Glenmark PAS; PX153, July 10, 2015 Glenmark PAS.

[24] PX155, Approval of Glenmark PAS for Alternate Drug Substance Source; PX147, Approval of Glenmark PAS for Alternative Supplier/Manufacturer.

[25] PX166, Dec. 12, 2007 Email from Soni to Krishan; PX168, Jan. 24, 2008 Email from Coughlin to Soni; PX169, Jan. 25, 2008 Email from Soni to Coughlin.

[26] *Id.*

[27] PX152, July 20, 2020 Email from Vaithara to Krishna.

[28] *Id.*; PX151, July 20, 2020 Email from Krishna to Vaithara.

[29] PX171, July 7, 2011 Email from Reddy to Soni; PX172, July 6, 2011 Email from Reddy to Soni.

[30] PX156, MSN Certificates of Analysis; PX042, J. Clark Report, ¶ 100.

B. Subsequent Generics

Teva filed its ANDA for generic Zetia on [redacted] Sandoz filed its ANDA for generic Zetia on April [redacted][32] [redacted][33] [redacted][34]

IV. THE EXPERT OPINIONS OF JON CLARK AND TODD CLARK

A. Jon Clark

Jon Clark is an FDA regulatory expert with over thirty-five years of experience in the pharmaceutical industry.[35] His experience includes twenty-one years at the FDA, including seven years as a Review Chemist and Electronic Submission Expert and ten years as Associate Director of Program Policy with the Office of Pharmaceutical Science, where he developed and implemented chemistry manufacturing and controls policy for the Center for Drug Evaluation and Research.[36] While at the FDA, he reviewed more than 200 market applications (including NDAs and ANDAs), over 500 supplements and over 700 DMFs.[37] At FDA, Jon Clark held several leadership roles setting guidelines on application, labeling and registration requirements and developing FDA "Guidance to Industry" documents.[38]

After leaving FDA, Jon Clark was Vice-President of Chemical Medicines and Industry Standards Collaboration at U.S. Pharmacopeia, which is a scientific nonprofit that sets compendial

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[31] PX208, Teva Original ANDA Submission.

[32] PX209, [redacted]

[33] PX206, Sandoz ANDA Cover Letter.

[34] PX207, [redacted]

[35] PX042, J. Clark Report, ¶ 3 & Ex. A.

[36] *Id.*, ¶ 3 & Ex. A.

[37] *Id.*, ¶ 4 & Ex. A.

[38] *Id.*, ¶ 4 & Ex. A.

standards for the identity, strength, quality and purity of medicines.[39] Since 2016, Jon Clark has worked as an independent consultant, specializing in FDA regulatory requirements for NDA and ANDA approval.[40] In this role, Jon Clark reviews NDA and ANDA submissions for pharmaceutical manufacturers and provides advice on FDA requirements on filings and approval.[41]

In his Report and Rebuttal Report, Jon Clark's opinions draw directly on his expertise concerning the regulatory requirements for ANDAs as well as his experience reviewing such applications, developing and implementing the guidelines governing such applications and working with generic manufacturers (both at the FDA and as a consultant) as they seek approval. Based on this expertise, Jon Clark opines:

- Glenmark's ANDA referencing the Process I DMF was eligible for approval on April 25, 2010.[42] A reasonable generic manufacturer in Glenmark's position would be incentivized to request FDA approval at the earliest opportunity.[43] If a reasonable generic manufacturer in Glenmark's position had requested approval of its ANDA in May of 2010, it would have received final approval no later than January 2011.[44]

- The Process II DMF was found adequate by the FDA by September 27, 2013. Glenmark's ANDA referencing the Process II DMF was eligible for approval on September 27, 2013.[45]

- The MSN DMF was found adequate by the FDA by August 15, 2013. If Glenmark's ANDA had referenced the MSN DMF earlier, which a reasonable generic manufacturer in Glenmark's position would have done, the ANDA referencing the MSN DMF would have been eligible for approval on August 15, 2013.[46]

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[39] *Id.*, ¶ 6 & Ex. A.

[40] *Id.*, ¶ 7 & Ex. A.

[41] *Id.*, ¶ 7 & Ex. A.

[42] *Id.*, ¶ 104.

[43] *Id.*, ¶ 108.

[44] PX043, J. Clark Rebuttal, at VI.

[45] PX042, J. Clark Report, ¶ 106.

[46] *Id.*, ¶ 107.

- A reasonable generic manufacturer in Glenmark's position, with an ANDA that was eligible for approval referencing an adequate DMF (the Process I DMF), would request final approval at its first opportunity and, after obtaining final approval, would submit post approval supplements referencing the MSN DMF and the Process II DMF.[47] Under this approach, a reasonable generic manufacturer in Glenmark's position would have FDA approval to manufacture generic Zetia using both the MSN DMF and the Process II DMF by September 27, 2013. [48]

- A reasonable generic manufacturer in Glenmark's position could have alternatively requested final approval after both the MSN DMF and the Process II were found adequate by the FDA. Under this approach, Glenmark's ANDA would have received final approval no later than June of 2014.[49]

Although seemingly styled as a motion to exclude all of the opinions of Jon Clark, Defendants do not mention or otherwise challenge the following opinions that he offers:

- Glenmark's ANDA was eligible for final approval on April 25, 2010.[50]

- If Glenmark had requested approval of its ANDA in May of 2010, it would have received final approval no later than January 2011.[51]

- The MSN DMF was adequate to support ANDA approval by August 15, 2013.[52]

- The Process II DMF was adequate to support ANDA approval by September 27, 2013.[53]

- A reasonable generic manufacturer in Glenmark's position could have requested final approval after both the MSN DMF and the Process II DMF were found adequate by the FDA. Under this approach, Glenmark's ANDA would have received final approval no later than June of 2014.[54]

As none of the above opinions have been specifically challenged in Defendants' Motion, they are

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[47] *Id.*, ¶ 108.

[48] PX043, J. Clark Rebuttal, at VI.

[49] PX042, J. Clark Report, ¶ 109; PX043, J. Clark Rebuttal, at VI.

[50] PX042, J. Clark Report, ¶ 104.

[51] PX043, J. Clark Rebuttal, at VI.

[52] PX042, J. Clark Report, ¶ 107.

[53] *Id.*, ¶ 106.

[54] *Id.*, ¶ 109.

not properly at issue and should not be excluded. Defendants only seek to exclude Jon Clark's opinion that a reasonable generic manufacturer in Glenmark's position, with an ANDA eligible for approval, would have requested final FDA approval at its first opportunity.

B. Todd Clark

Todd Clark is a pharmaceutical consultant with twenty-five years of experience in the pharmaceutical industry.[55] He has been retained by numerous branded and generic drug companies, biotech firms, investment banks, and health technology services companies to advise them on global strategies regarding drug development, clinical trial design, market entry, intellectual property issues, regulatory compliance, forecasting, marketing strategy, competitive intelligence, pricing, reimbursement, and allocation of promotional resources.[56] He is the author of seven editions of *PharmaHandbook — A Guide to the International Pharmaceutical Industry*®, a single-source reference guide on pharmaceutical business and regulatory environments in 39 countries, and three editions of *GenericHandbook – A Guide to the US Generic Pharmaceutical Industry*™, a comprehensive reference guide to the marketing, intellectual property, legal, regulatory, and competitive aspects of the generic drug sector in the United States.[57]

Here, he opines that, if Glenmark had entered into a settlement agreement permitting it to introduce generic ezetimibe earlier than December 12, 2016, multiple subsequent generic manufacturers would have entered earlier than they actually entered.[58] In particular, he opines that Teva and Sandoz would have obtained final approval and launched generic Zetia earlier if Glenmark's 180-day exclusivity expired earlier than it actually did. Teva and Sandoz would have

[55] PX044, T. Clark Report, ¶ 3.

[56] *Id.*, ¶ 3.

[57] *Id.*, ¶ 3, Ex. 1, CV at 1.

[58] *Id.*, ¶ 15.

launched at the end of Glenmark's 180-day exclusivity period if that date was after the date [redacted].[59] In reaching these conclusions, Todd Clark relied on: (1) the powerful financial incentives of generic companies to obtain final approval and prepare to launch at the earliest opportunity, particularly on multi-billion dollar drugs like Zetia;[60] (2) the fact that [redacted]"[61] (3) the fact that Teva and Sandoz (and others) [redacted][62] (4) the fact that neither Teva nor Sandoz, two of the world's largest generic drug companies, [redacted] and the [redacted];[63] and (5) the fact that that Teva and Sandoz's (and others') [redacted]

[59] *Id.*, ¶ 15.

[60] *Id.*, ¶¶ 28-35.

[61] *Id.*, ¶ 57.

[62] *Id.*, ¶ 55 [redacted]

[63] *See generally id.* ¶¶ 59-62 & 72-79; PX045, Rebuttal Expert Report of Todd Clark ("T. Clark Rebuttal"), ¶¶ 38-41.

[redacted].[64]

Defendants challenge Todd Clark's opinion because it relies in part on the [redacted] arguing that Todd Clark did not provide any opinion as to whether [redacted] had Merck not paid Glenmark to avoid the risk of patent litigation and delay generic entry.

V. LEGAL STANDARD

A. Standard For Defendants' Motion To Exclude

Federal Rule of Civil Procedure 702 provides that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and[,]
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702's requirement "that the evidence or testimony '[help] the trier of fact to understand the evidence or to determine a fact in issue'" goes primarily to relevance.[65]

Although experiential testimony does not rely on the scientific method, "this does not lead to a conclusion that 'experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis

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[64] PX044, T. Clark Report, ¶¶ 55, 67; PX045, T. Clark Rebuttal, at ¶ 19 [redacted] ¶ 20 [redacted]

[65] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591 (1993) (quoting Fed. R. Evid. 702).

of experience.'"[66] When a party challenges an expert's qualifications, "the test for exclusion is a strict one, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is proffered."[67]

It is for the jury "to evaluate the reliability of the underlying data, assumptions, and conclusions."[68]

VI. ARGUMENT

A. Jon Clark's Opinions Satisfy *Daubert* And Are Admissible.

Defendants ask the Court to exclude Jon Clark's opinion that a reasonable firm in Glenmark's position would seek to come to market as soon as possible because they claim that: (1) Jon Clark has no methodology to determine how a "reasonable generic firm" would act and his opinion is "impermissible *ipse dixit*"; (2) Jon Clark's opinions are inconsistent with the facts because Glenmark did not seek approval as soon as possible, the way that he says a reasonable generic company would; and (3) Jon Clark's opinion about what a reasonable generic company in Glenmark's position would do is irrelevant. None of these arguments is sufficient to preclude Jon Clark's relevant and helpful testimony about what a reasonable generic company seeking to come to market would do.

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[66] *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (quoting Fed. R. Evid. 702 advisory committee's note).

[67] *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993) (quoting *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989)).

[68] *In re Urethane Antitrust Litig.*, 768 F.3d 1245, 1263 (10th Cir. 2014); *see also Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013) ("Rule 702[] . . . does not ordinarily extend to the reliability of the conclusions [an expert's] methods produce – that is, whether the conclusions are unimpeachable.") (quoting *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 765 (7th Cir. 2013)); *In re Sulfuric Acid Antitrust Litig.*, 743 F. Supp. 2d 827, 866 (N.D. Ill. 2010) ("The credibility and persuasiveness of Plaintiffs' expert witnesses are issues best left to a factfinder.").

1. Jon Clark's Opinions Are Based On His Extensive Experience At The FDA And His Review Of Regulatory Documents In The Case.

Contrary to Defendants' argument,[69] Jon Clark has an adequate methodology and basis for his opinions. His opinions are based on his experience at the FDA and his understanding of the complex regulatory approval process for ANDAs. Accordingly, his opinions are appropriate under Rule 702.

Experiential testimony like Jon Clark's "does not lead to a conclusion that 'experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience.'"[70] "[T]o be qualified under Rule 702, an experiential expert witness [must] explain how [his or her] experience leads to the conclusion reached, why [his or her] experience is a sufficient basis for the opinion, and how [his or her] experience is reliably applied to the facts."[71]

Jon Clark spent twenty-one years at the FDA, during which time he reviewed more than 200 market applications (including NDAs and ANDAs), over 500 supplements and over 700 DMFs.[72] As part of these reviews, Jon Clark routinely corresponded with pharmaceutical manufacturers as they pursued the approval of their applications. At FDA, he developed and implemented numerous FDA policies for the Center for Drug Evaluation and Research, which included FDA "Guidance to Industry" documents and FDA guidelines for the review of NDAs,

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[69] Defs' Mem. at 11.

[70] *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (quoting Fed. R. Evid. 702 advisory committee's note).

[71] *Wood v. Credit One Bank*, 277 F. Supp. 3d 821, 855–56 (E.D. Va. 2017) (quoting Fed. R. Evid. 702 advisory committee's note).

[72] PX042, J. Clark Report, ¶¶ 3-4 & Ex. A.

ANDAs, and DMFs.[73] In addition to his experience at FDA, Jon Clark has provided consulting services for numerous brand and generic manufacturers concerning the FDA regulatory requirements for achieving NDA and ANDA approvals.[74] Jon Clark has substantial experience with what generic manufacturers do when they are trying to obtain FDA approval to come to market, because he has seen what they do while at the FDA and from his consulting practice.[75] Based on his expertise and the facts of record, Jon Clark identified the points in time at which earlier ANDA approval was available to Glenmark, referencing the Process I DMF, Process II DMF, and MSN DMF.[76] Further, he identified the pathway for approval that a reasonable generic, seeking earlier approval, would take given the regulatory landscape that Glenmark faced.[77] Contrary to Defendants' argument, Jon Clark did not need to have "worked at a generic firm" or to have had "decision-making responsibility for a generic firm's [ANDA] strategy"[78] to form his opinions in this case. Rather, while at the FDA and as a consultant, he has worked with scores of pharmaceutical manufacturers as they sought approval of their drug products, and he bases his opinions on how a reasonable generic would act based on that extensive and broad experience.[79]

Defendants' reliance on *In re Namenda Direct Purchaser Antitrust Litig.*[80] is misplaced.

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[73] *Id.*, ¶ 4 & Ex. A.

[74] *Id.*, ¶ 7 & Ex. A.

[75] *Id.*, ¶ 7 & Ex. A.

[76] *See, e.g., id.*, ¶¶ 104-107.

[77] *See, e.g.*, *id.*, ¶¶ 108-109.

[78] Defs' Mem. at 11.

[79] *See* PX076, Tr. of July 8, 2020 Dep. of Jon Clark ("J. Clark Dep."), at 106:13-19 ("In my experience with review work, consulting work and everything, I would expect a generic firm who is interested in getting approved and on the market, especially one with an exclusivity, I would expect them to get the approval they can get, when they can get it …").

[80] *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152 (S.D.N.Y. 2018).

In *Namenda*, the court excluded the expert's opinions because they largely regurgitated the testimony of fact witnesses.[81] Here, Jon Clark's opinions are based on his review and interpretation of Glenmark's ANDA and other regulatory documents and his own experience reviewing and advising manufacturers concerning such applications. There is no single document or group of documents that show how Glenmark would have obtained approval to come to market earlier absent its illegal agreement with Merck. Jon Clark's expertise will help the jury to understand the regulatory issues and decide when a reasonable company in Glenmark's position was likely to have obtained regulatory approval absent the agreement to stay off the market until December 2016.[82]

2. Jon Clark's Opinions Are Consistent With The Facts And The Requisite Legal Standard

Defendants argue that Jon Clark's opinion that a reasonable generic in Glenmark's position would have sought earlier approval is inconsistent with the facts because Glenmark did not act the way that Jon Clark says a reasonable generic company would act. They say his opinion must be excluded because Glenmark did not seek approval as soon as possible in 2010, as Jon Clark opines

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[81] *See id.* at 172 ("the only thing [the] 'expert' opinion does is bolster the credibility of the 30(b)(6) witnesses").

[82] *See e.g.*, *Antrim Pharm. LLC v. Bio-Pharm, Inc.*, 950 F.3d 423, 430-31 (7th Cir. 2020) (allowing expert to opine on the implications of certain FDA regulations "when that testimony assists the jury in understanding a party's actions within that broader framework"); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 478-79 (S.D.N.Y. 2016) (same).

Defendants' citation to *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323 (S.D. Fla. 2010) likewise fails. In *Trasylol* the expert opinion "mostly consists of a factual narrative of Trasylol's regulatory history and summaries of Bayer's internal documents. Dr. Parisian does not analyze the facts; she … regurgitates them and reaches conclusory opinions" including "opinions regarding Bayer's and the FDA's state of mind and knowledge[.]" *Id.* at 1346. Jon Clark's analysis of Glenmark's ANDA and its earlier opportunities for approval, among other things, differ substantially from the conclusory opinions that were excluded in *Trasylol*. Defendants' citation to *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194 (4th Cir. 2001), which concerns expert opinions on the safety of a medical device, should also be disregarded.

a reasonable company would do, but rather waited until 2014. Far from representing a reason to preclude Jon Clark's opinions, the difference between what Glenmark actually did and what a reasonable generic company would do is precisely why Jon Clark's opinion is helpful to the jury.

Glenmark did not actually seek regulatory approval as soon as possible because Merck paid it, with the no-AG agreement, not to enter until December 2016. The question that the jury must answer is whether a reasonable company in Glenmark's position would have acted differently absent that payment.[83] Jon Clark's opinion will assist the jury to determine how a reasonable company would act absent the conduct challenged in this case.[84]

Jon Clark describes "two options" that were available to Glenmark "for obtaining earlier approval of its ANDA." And, based on his experience working with and advising generics, he explained that a generic manufacturer will seek approval at the earliest opportunity.[85] By providing a road map as to what a reasonable generic company seeking to come to market will do, Jon Clark's opinions will assist the jury to assess whether a reasonable company in Glenmark's position would have been able to get approval earlier. If the jury gets to the causation stage, it will have already concluded that Merck paid Glenmark to delay its generic entry. The actual conduct

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[83] *See, e.g., United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA* ("*Lidoderm*"), 296 F. Supp. 3d 1142, 1162 (N.D. Cal. 2017) (noting that in "the antitrust context . . . profit-maximizing goals [are] assumed"); *id.* at 1179 n.42 ("in construct[ing] but-for world scenarios, there is a presumption of economic rationality").

[84] *See Kleen Prods. LLC v. Int'l Paper Co.*, 831 F.3d 919, 927 (7th Cir. 2016) (a plaintiff may establish antitrust injury through "an expert construction of a hypothetical market free of any anticompetitive restraint"); *In re Asacol*, 323 F.R.D. at 488 (explaining that "in antitrust suits, juries are allowed to act on probable and inferential as well as (upon) direct and positive proof") (internal quotation omitted))

[85] PX076, Jon Clark Dep., at 106:13-19 ("In my experience with review work, consulting work and everything, I would expect a generic firm who is interested in getting approved and on the market, especially one with an exclusivity, I would expect them to get the approval they can get, when they can get it …").

of an antitrust violator does not limit how a reasonable company would act in the hypothetical world absent the challenged conduct.[86] Because Jon Clark's opinions are consistent with the record, and are part of the evidence that purchasers offer to establish a benchmark for what would have happened absent Defendants' reverse payment, Defendants' argument should be rejected.

3. Jon Clark's Opinions Are Relevant To The Causation Issues In This Case.

Defendants argue that Jon Clark's opinions concerning a "hypothetical reasonable generic firm [are] irrelevant and unhelpful to the jury in understanding the circumstance confronting Glenmark in this case."[87] Defendants are wrong.

In analyzing causation, the relevant question is how a reasonable company seeking to maximize its profits would have acted absent the unlawful conduct.[88] The opinions in Jon Clark's Report and Rebuttal Report answer this question:

> In my opinion, a reasonable generic manufacturer in Glenmark's position, with an ANDA that is eligible for approval with reference to an adequate DMF [the Process I DMF], would request final approval at its first opportunity. If there is a better source of API available, either because of regulatory, technical, safety or economic reasons, a reasonable generic manufacturer in Glenmark's position would request final approval and then change the API supplier after approval";[89]

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[86] *See Lidoderm*, 296 F. Supp. 3d at 1190 (rejecting argument that expert's opinion is not based on sufficient facts in the record, "[b]ecause this case is set in a but-for world, it is not surprising that no evidence shows that defendants were contemplating anything other than the actual Settlement"); *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *21 (D. Mass. Jan. 25, 2018).

[87] Defs' Mem. at 14.

[88] *See, e.g.*, *Lidoderm*, 296 F. Supp. 3d at 1162 (noting that in "the antitrust context . . . profit-maximizing goals [are] assumed"); *id*. at 1179 n.42 ("in construct[ing] but-for world scenarios, there is a presumption of economic rationality"); *Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985) (holding that the plaintiff "must presume the existence of rational economic behavior" in a "hypothetical free market" absent "the anticompetitive activity"); *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *21 (D. Mass. Jan. 25, 2018) (discussing the evidence necessary to establish "rational, lawful business choices" in support of a "but-for theory of causation").

[89] PX042, J. Clark Report, ¶108.

> An alternative approach to this approval process would be to delay the request for final approval until all of the API sources are included through amending the ANDA before it is approved … Under this approach, a reasonable generic manufacturer in Glenmark's position would request final approval at the time that both [the MSN DMF] (August 15, 2013) and [the Process II DMF] (September 27, 2013) were found adequate;[90]
>
> Glenmark had two options for obtaining earlier approval of its ANDA … These two timelines are set forth in detail below.[91]

At his deposition, Jon Clark further explained that reasonable generic companies seek to get approval as soon as possible and identified how Glenmark could have done so.[92]

Defendants' cases are inapplicable. *In re TMI Litig.*,[93] *Trana Discovery, Inc. v. Southern Research Institute*,[94] and *Wise v. C.R. Bard, Inc.*,[95] are not antitrust cases and do not address expert testimony relevant to establishing a hypothetical but-for causation theory. And, in *Concord Boat Corp.* and *El Aguila*, expert opinion testimony was excluded because the expert ignored relevant and substantial parts of the record.[96] As set forth above, Jon Clark's opinions as to opportunities

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[90] *Id.*, ¶109.

[91] PX043 J. Clark Rebuttal, ¶50 (detailed charts setting forth each regulatory step for the earlier approval of Glenmark's ANDA).

[92] PX076, J. Clark Dep., at 108:6-10 ("in all of my experience, Timeline A is used. And, in fact, firms looking at approval will get that approval they can get, when they can get it, even if it means dropping parts of the application to get it."); *id*. at 106:13-19 ("In my experience with review work, consulting work and everything, I would expect a generic firm who is interested in getting approved and on the market, especially one with an exclusivity, I would expect them to get the approval they can get, when they can get it …").

[93] *In re TMI Litig.*, 193 F.3d 613 (3d Cir. 1999).

[94] *Trana Discovery, Inc. v. Southern Research Institute*, 915 F.3d 249 (4th Cir. 2019).

[95] *Wise v. C.R. Bard, Inc.*, 2015 WL 521202 (S.D. W. Va. Feb. 7, 2015).

[96] *See Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056-57 (8th Cir. 2000) ("[n]ot all relevant circumstances were incorporated into the expert's method of analysis" and the expert "ignored inconvenient evidence" and "failed to account for market events"); *El Aguila Food Prod., Inc. v. Gruma Corp.*, 131 F. App'x 450, 454 (5th Cir. 2005) (expert "did not examine sales data from retailers in the relevant markets to determine whether space allocation among the various

for earlier ANDA approval and what a reasonable generic in Glenmark's position would do are based entirely on the facts of record and his experience working with pharmaceutical manufacturers seeking regulatory approval.

Defendants' claim that Jon Clark "made no attempt to understand Glenmark's decision-making process and why it was different from what he would expect" does not justify the exclusion of Jon Clark's opinion.[97] Jon Clark does not offer an opinion on the reasons why Glenmark delayed seeking approval. Jon Clark's deposition testimony was clear on this point.[98] There is no need for Jon Clark to offer an opinion on why Glenmark acted the way that it did in the actual world. If the jury gets to the question of causation, it will have already answered that question: Glenmark did not act like a reasonable generic company because it violated the antitrust laws by entering into the no-AG agreement with Merck in exchange for delaying generic entry. The jury's task at the causation stage is to identify a benchmark to isolate the effects of that conduct. Jon Clark's opinion on how a reasonable generic company would have acted is directly relevant to that question and should not be excluded.

B. Todd Clark's Challenged Opinions Are Reliable

1. Todd Clark's Opinions Regarding Teva's And Sandoz's Abilities To Introduce Generic Zetia Before December 2016 Are Properly Based On His Experience And The Evidence.

Defendants argue that Todd Clark's opinions that Teva and Sandoz were likely to enter earlier if Glenmark entered earlier are unreliable because he did not use the kind of modelling that

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brands was disproportionate to their sales" among other things).

[97] Defs' Mem. at 13.

[98] PX076, J. Clark Dep., at 145:24-146:4 ("I'm just saying that the actions I would have expected, I've laid out. Those actions didn't happen. I expect a reasonable firm to follow those actions. Glenmark did not. I don't know why.").

they claim he uses in his consulting practice to predict whether other generic entrants would enter the market.[99] However, the Monte Carlo Analysis ("MCA") that Defendants point to is a methodology that Todd Clark uses when he has little or no information about the potential generic entrants.[100] The MCA is a less accurate substitute for actual data when such data is not available. That is not the case here, where the discovery record and the benefit of hindsight provide significant actual information about the potential entrants.

As Todd Clark explains in his reports and deposition, here, he considered testimony and contemporaneous internal documents from Teva and Sandoz, as well as their [redacted] This information allowed him to apply his experience to the actual ANDAs filed by Teva and Sandoz to form opinions concerning when they would have likely been able to get approval and launch if Glenmark had entered the market earlier. Models like MCA based on competitive intelligence are inferior to conclusions based on a full record of real world information produced in discovery.[101] Here, Todd Clark had the benefit of considering the actual ANDAs filed by Teva and Sandoz and approved by the FDA, the economic attractiveness of the opportunity to introduce generic Zetia, the degree of difficulty involved in making the drug,[102] the time that it took other generic applicants to get approval for their generic Zetia ANDAs, and the time frame in which Teva and Sandoz got approval for their generic versions of Zetia in other countries with comparable regulatory requirements but without the 180-

[99] Defs' Mem. at 16-17.

[100] PX077, Tr. of July 2, 2020 Dep. of Todd Clark ("T. Clark Dep."), at 56:07-65:13 (explaining that for non-litigation consulting, forward-looking models based on press releases and competitive intelligence may be used, e.g., to quantify the players expected in injectables or biosimilars).

[101] PX077, T. Clark Dep., at 23:11-12 ("I had access to the full record").

[102] *Id.*, at 100:03-102:03 (opinions are based on "[t]he totality of the evidence and my experience as opposed to a spreadsheet").

day exclusivity barrier. Defendants' argument rests on the false premise that there is only one way to estimate the timing of generic entry applicable in all situations. But different situations call for different analyses. As Todd Clark testified, there are many types of models.[103] The Fourth Circuit has similarly recognized: "Choosing the test to apply is a matter of selecting the appropriate tool for the task, and involves consideration of a variety of factors including the type of data."[104] Todd Clark's consideration of the specific evidence concerning the approval and launch of the Teva and Sandoz's generic versions of Zetia does just that. There was no need for him to ignore more accurate actual data and instead rely on a purely statistical approach such as MCA.

Experts like Todd Clark are permitted to apply their experience to the facts as he did in this case.[105] In fact, another court allowed Todd Clark to offer such opinions in a similar delayed-generic-entry pharmaceutical antitrust case despite a challenge similar to that asserted here by defendants.[106] Defendants do not contest that Todd Clark analyzed the relevant documents and testimony or used appropriate benchmarks and analogues, in light of his experience, to opine on entry timing.[107]

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[103] *Id.*, at 101:10-102:03.

[104] *In re Lipitor (Atorvastatin Calcium)*, 892 F.3d. 624, 634 (4th Cir. 2020).

[105] *See, e.g.*, *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) ("But no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."); *Morgan v. On Deck Capital, Inc.*, 2019 WL 4093754 (W.D. Va. Aug. 29, 2019) (allowing those expert opinions based upon accurate facts and expert's decades experience); *Franklin v. Home Depot U.S.A.*, 2007 WL 8081421 (W.D. Va. June 16, 2007) (allowing those expert opinions based upon accurate facts and expert's decades experience).

[106] *In re Asacol Antitrust Litig.*, 323 F.R.D. 451, 466-67 (D. Mass. 2017) (allowing Todd Clark's opinions regarding timing and extent of generic entry where he used historical information and his experience rather than a "quantitative simulation").

[107] Like the defendant in *Krakauer v. Dish Network, L.L.C.*, Defendants do not challenge Todd Clark's qualifications, his data or contend his methodology was unsound, but merely that he did not use a deterministic model. 2015 WL 5227693, at *14 (M.D.N.C. Sept. 8, 2015) (observing the court must "determine reliability in light of the proposed expert's full range of experience and training as well as the methodology used to arrive at a particular conclusion.") (quoting *Am. Honda*

Unlike the excluded expert in *In re Lipitor*, Todd Clark's opinions about the approval and launch timing of Teva and Sandoz are not based on cherry-picked data outside his area of expertise.[108] Todd Clark considered the historical facts, including (i) [redacted];[109] (ii) [redacted];[110] (iii) the ability of multiple less-sophisticated generic companies to obtain FDA approval and commercialize generic Zetia on a substantially more accelerated basis than these global generic giants when needed to meet the target launch date;[111] (iv) the approval of Teva and Sandoz's Zetia generics in other countries with similar drug regulatory systems long before their approval in the U.S.;[112] and (v) Rule 30(b)(6) testimony from Teva and Sandoz that [redacted] by the agreement between Glenmark and Merck and the resulting bottleneck preventing the final approval of subsequent generics.[113]

Citing *Holesapple*,[114] Defendants assert that Todd Clark's opinions should be excluded as merely his "say-so." But the *Holesapple* court excluded the admiralty expert in a maritime negligence case because he did *not* consider "standard indicia" relevant to the accident such as weather reports, wave height, and reports from nearby vessels: "All of these factors should have

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Motor Co. v. Allen, 600 F. 3d 813, 816 (7th Cir. 2009)).

[108] *In re Lipitor*, 892 F.3d at 636-38.

[109] PX044, T. Clark Report, ¶¶ 52, 57, 70.

[110] *Id.*, ¶¶ 58, 72.

[111] *Id.*, ¶¶ 49-52.

[112] PX045, T. Clark Rebuttal, ¶¶ 32-37.

[113] PX044, T. Clark Report, ¶¶ 59-61, 73-79.

[114] *Holesapple v. Barrett*, 5 F. App'x 177 (4th Cir. 2001).

been considered by the expert, in order to show that he had formed an opinion based on the facts of the particular incident rather than making an 'opinion' judgment based entirely on what he considers to be his experience, together with having reviewed the depositions."[115] In contrast, Todd Clark clearly explained how his opinions were based on his decades of industry experience applied to the facts from discovery, relevant analogues and benchmarks, and extensive review of academic and industry literature.

Defendants further criticize Todd Clark for having no quantitative model to support his testimony "that he is 'roughly 95[%] plus confident' that Teva and Sandoz would have launched in the but-for world on the dates of [redacted]."[116] But Defendants are raising a red herring. This is not an opinion that Todd Clark included in his report. It was a response to Defendants' questions at deposition asking Todd Clark to assign a value to the confidence he had in his opinions.[117]

2. [redacted] Were Not Part Of, Nor Caused By, The Antitrust Violation And Therefore Remain In The But-For World.

Defendants further argue that the Court should exclude Todd Clark's opinion about Teva and Sandoz's earlier entry because he failed to [redacted]."[118] Defendants' argument imposes an improper burden on purchasers to prove that [redacted]

[115] *Id.* at 180.

[116] Defs' Mem. at 17.

[117] PX077, T. Clark Dep., at 97:02-09 ("nor do I assign a number to that in the opinion. . . . But you're asking me . . . and probably well north of 95 percent.").

[118] Defs' Mem. at 18.

absent Defendants' violation. There is no such burden. When constructing a but-for world, everything from the actual world remains the same except for the antitrust violation and its anticompetitive effects.[119] Here, there is no claim or evidence that the [redacted] causes *because* of Merck's offer of a no-AG provision to Glenmark. Because [redacted] are not part of this antitrust violation or affected in any way by it, as a matter of law, [redacted] must remain unchanged in the but-for world.[120] Thus, an expert offering an opinion relevant to the but-for world need not specifically opine on whether conduct that occurred for reasons unrelated to the violation would remain in the but-for world.

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[119] *See Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 259, 263 (1946) (referring to proof of plaintiff's experience "in the absence of" the restraints or "if the restraints had not been imposed"); *Nat'l Farmers Org., Inc. v. Associated Milk Producers, Inc.*, 850 F.2d 1286, 1306 (8th Cir. 1988) (stating that damages measure "the difference between [plaintiff's] performance in a hypothetical market free of all antitrust violations and its actual performance in the market infected by anticompetitive conduct"); *Kleen Prods. LLC v. Int'l Paper Co.*, 831 F.3d 919, 927 (7th Cir. 2016) (explaining that a "plaintiff could satisfy its burden" to establish antitrust injury through "an expert construction of a hypothetical market free of any anticompetitive restraint"); *Blades v. Monsanto Co.*, 400 F.3d 562, 569 (8th Cir. 2005) (explaining that hypothetical market must be "free of the restraints and conduct alleged to be anticompetitive") (quoting *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir. 2000)); *Exhaust Unlimited, Inc. v. Cintas Corp.*, 223 F.R.D. 506, 513 (S.D. Ill. 2004) ("To establish impact, an expert must 'construct a hypothetical market, a but-for market, free of the restraints and conduct alleged to be anticompetitive.'") (quoting *Sample v. Monsanto Co.*, 218 F.R.D. 644, 650 (E.D. Mo. 2003)); *Apotex, Inc. v. Cephalon, Inc.*, 321 F.R.D. 220, 236 (E.D. Pa. 2017) ("When recreating a but-for world to establish antitrust damages, a plaintiff must create a world 'characterized by the absence of the . . . challenged practices.'") (quoting *Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Grp., L.P.*, 247 F.R.D. 156, 165 (C.D. Cal. 2007)).

[120] *In re Disposable Contact Lens Antitrust Litig.*, 329 F.R.D. 336, 419 (M.D. Fla. 2018) ("A properly defined 'but for' world is one in which all aspects of the actual world remain unchanged except for the effects *caused* by the restraint of trade at issue. Defendants' experts misapprehended the correct definition of the but-for world, which leads them to focus mistakenly on insurance reimbursements, rebates and discounts, all of which would have remained unchanged in the 'but for' world."); *In re Blood Reagents Antitrust Litig.*, 2015 WL 6123211, at *16 (E.D. Pa. Oct. 19, 2015) (damages expert needs not account for increases in demand where there was "no evidence in the record that TBR price increases were caused by increases in aggregate demand for blood").

Todd Clark relied on the [redacted],[121] which are not challenged as anticompetitive.[122] His reports explain at length that [redacted].[123] This testimony is sufficient to meet purchasers' burden with respect to the [redacted] By contrast, Defendants have presented no evidence, no expert opinion, nothing whatsoever, to contest Clark's opinion that [redacted] or to suggest they were included only because of the unlawful aspects of the Merck-Glenmark settlement. Clark therefore need not go any further to explain why an element typically included in [redacted]

[121] PX044, T. Clark Report. ¶ 55 [redacted] *id.* at ¶ 61 [redacted] citing PX203, [redacted] PX044, T. Clark Report, ¶ 67 [redacted] citing PX067, T. Brown Dep. Ex. 28 [redacted] *id.* at ¶ 78 [redacted]

[122] *See., e.g.*, PX044, T. Clark Report, ¶ 42 [redacted] PX045, T. Clark Rebuttal, ¶ 20 [redacted]

[123] PX045, T. Clark Rebuttal, ¶ 15 [redacted]

and that are not challenged as anticompetitive, would also occur in the but-for world. They exist in the actual world and would exist in a world without Merck and Glenmark's unlawful conduct, because [redacted]

The only case Defendants cite on this point, *Lee v. City of Richmond*,[124] has nothing to do with the standard for an expert opinion regarding the but-for world in an antitrust case, and provides no support for their argument. In that case, the court rejected an expert opinion regarding the appropriate standard of conduct for a police officer using deadly force because the proposed expert admitted that "I don't know what the standard is and you don't know what the standard is and nobody is really going to be able to really nail that standard down."[125] The judge rejected the opinion because the expert "has reduced his opinions on compliance to *ipse dixit* entirely devoid of meaningful principles."[126] In contrast, Clark more-than-adequately explains [redacted]. His observations on the issue are not *ipse dixit* but rather [redacted], as well as his extensive knowledge and decades of experience with generic drug development and commercialization, and the incentives and regulatory system governing them.

[124] *Lee v. City of Richmond*, 2014 WL 5092715, at *7 (E.D. Va. Sept. 30, 2014).

[125] *Id.*

[126] *Id.*

VII. CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude Proposed Expert Opinions and Testimony of Plaintiffs' Generic Launch Timing Expert Jon Clark and Todd Clark should be denied.

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CERTIFICATE OF SERVICE

I, Adam M. Carroll, certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: September 11, 2020 /s/ Adam M. Carroll